

REMARKS

This Response is submitted in reply to the final Office Action mailed on September 26, 2007. A Request for Continued Examination is submitted herewith. The Director is authorized to charge any fees that may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112701-780 on the account statement.

Claims 1, 3, 4, 6-10 and 13-20 are pending in this application. Claims 2, 5 and 11-12 have previously been canceled. Claims 1, 3, 4, 6-10 and 13-20 are rejected under 35 U.S.C. §112 and §103. In response, Applicants amend Claim 14. The amendment does not add new matter. In view of the amendment and for the reasons set forth below, Applicants respectfully submit that the rejections should be withdrawn.

In the Office Action, Claim 14 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claims the subject matter which applicant regards as the invention. Specifically, the Patent Office asserts that it is unclear which protein of Claim 13 is being referred to in Claim 14. In response, Applicants amend Claim 14 to recite the infant formula of claim 13 comprising from 9.0 to 10.0 w/w% of all protein sources contained in the infant formula. Applicants respectfully submit that Claim 14, as amended, distinctly claims the subject matter that Applicants regard as the invention.

Applicants' specification establishes that the "protein" recited in Claim 14 refers to the concentration of all protein contained in Applicants' claimed composition. For example, the specification states that to be as close as possible to human milk, the protein in infant formulae may be derived from both whey and casein in an appropriate ratio. However, a high protein concentration is necessary to ensure the infant gets the necessary amount of all essential amino acids, which results in an infant's metabolism being susceptible to overloading with nitrogen from the protein intake. See, specification, page 1, lines 29-36.

To address this, Applicants have provided a composition, which comprises as recited in Claim 13, for example, hydrolysed sweet whey protein, from which casino-glyco-macropetide has been removed; casein protein; free arginine; free histidine; and milk protein comprising 5% or more of tryptophan. This composition can comprise from about 9.0 to about 10.0 w/w% of protein, which provides the advantage of being equivalent to the amount of protein generally

present in human milk and that corresponds to the lower limit tolerated by codex alimentarius. See, specification, page 3, lines 5-10. Since Applicants' composition comprises multiple sources of protein similar to that asserted as necessary to be as close as possible to human milk, the "protein" of Claim 14 describes the concentration of all protein contained in the composition. Moreover, the percentage claimed provides the advantage described above, which avoids the problem of high protein concentrations and high nitrogen levels existing in standard formulae.

Accordingly, Applicants request that the rejection of Claim 14 under 35 U.S.C. §112, second paragraph, be withdrawn.

In the Office Action, Claims 1, 3-4, 6-10 and 13-20 are rejected under 35 U.S.C. §103(a) as being unpatentable over JP 002158762 to Yonekubo et al. ("*Yonekubo*") in view of U.S. Patent No. 5,916,621 to Georgi et al. ("*Georgi*"). Applicants believe this rejection is improper and respectfully traverse it for at least the reasons set forth below.

Independent Claims 1, 10, 13 and 20 recite, in part, an infant formula comprising hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed, and a milk protein comprising 5% or more of tryptophan. In contrast, Applicants respectfully submit that, the cited references are not combinable and, even if combinable, fail to disclose or suggest every element of the present claims.

The cited references are not combinable because *Yonekubo* teaches away from combining the cited references to arrive at the present claims. The Patent office takes the position that, while *Yonekubo* does not teach the use of hydrolysed sweet whey protein from which caseino-glyco-macropeptide (CGM) has been removed, *Georgi* remedies this deficiency by teaching to use of sweet whey protein produced by the precipitation and removal of caseins, whereby CGM must be removed by suitable processes. See, Office Action, page 5, lines 18 to page 6, line 15. The Patent Office further asserts that *Georgi* recognizes the need for whey protein with a reduced threonine content. However, this proposed combination ignores the fact that the examples in *Yonekubo* disclose compositions containing added threonine. See, *Yonekubo*, page 2, lines 1-5; page 3, lines 1-5; and page 4, Practical Example 1. Therefore, regardless of *Georgi's* alleged disclosures regarding the need and use of sweet whey protein with reduced CGM and threonine content, *Yonekubo* teaches away from the use and need of such manipulated proteins by teaching the addition of threonine to its compositions. Further, the addition of

threonine would negate the effects of reduced threonine whey protein anyway, making *Georgi's* alleged teachings relatively useless in the compositions of *Yonekubo*.

Even if the cited references are not combinable, Applicants respectfully submit the cited art fails to disclose or suggest every element of the present claims. For Example, *Yonekubo* fails to disclose or suggest a composition comprising a milk protein comprising 5% or more of tryptophan as required, in part, by independent Claims 1, 10, 13 and 20. *Georgi* fails to remedy this deficiency, for the Patent Office only relies on *Georgi* to assert that *Georgi* teaches the use of hydrolyzed sweet whey protein from which CGM has been removed. Consequently, the cited references fail to teach a composition comprising a milk protein comprising 5% or more of tryptophan.

The Patent Office asserts, however, that *Yonekubo* teaches that casein, a tryptophan-rich milk protein, is at 24-32% by weight and has a level of 5% or more of tryptophan. See, Office Action, page 5, lines 12-13. Applicants respectfully disagree. *Yonekubo* never teaches a milk protein having 5% or more of tryptophan. Instead, *Yonekubo* teaches adding L-tryptophan as a separate or free ingredient in the composition. Each time *Yonekubo* discloses using tryptophan, the ingredient appears as a separate addition to the composition, not as a sub-component of another ingredient. See, *Yonekubo* (English translation), page 2, lines 1-5; page 3, lines 1-5; and page 4, Practical Example 1. Further, in the only example disclosed in *Yonekubo*, tryptophan has a separate weight value, clearly indicating that tryptophan is a separately added ingredient. Moreover, if the Patent Office's assertion is indeed correct, tryptophan would be a sub-component of sodium caseinate. However, in Practical Example 1, whey powder is listed between sodium caseinate and the amino acid list (including tryptophan), which makes the assertion even more unlikely.

Further, even assuming sodium caseinate includes tryptophan, sodium caseinate is not a tryptophan-rich milk protein. In fact, one skilled in the art would know that sodium caseinate generally has a much lower amount of tryptophan than that required in the present claims. Specifically, sodium caseinate generally contains about 1.1% tryptophan. See, for example, www.americancasein.com/docs/Sodium%20Caseinate.doc; <http://www.casein.com/products.htm>; <http://sci-toys.com/ingredients/casein.html>. Consequently, *Yonekubo* fails to disclose or suggest a milk protein comprising 5% or more of tryptophan as required by the present claims.

The Patent Office further takes the position that *Yonekubo* teaches compositions comprising natural milk proteins, whey powder, amino acids, nutrients and carbohydrates and that, because *Yonekubo* teaches whey protein in terms of milk protein serum protein, *Yonekubo* inherently teaches whey protein with high tryptophan content. However, Applicants point out that *Yonekubo* specifically teaches "the amino acids are generally used in free form, but it is possible to use histidine in hydrochloride form." See, *Yonekubo*, page 3, lines 24-25. Therefore, regardless of what the Patent Office asserts is inherently taught by *Yonekubo*, it is plainly stated that amino acids are added in free form, with the only stated outlier being histidine, not tryptophan.

For the reasons discussed above, the references are not combinable and, even if combinable, *Yonekubo* and *Georgi* do not teach, suggest, or even disclose all of the elements of the present claims, and thus, fail to render the claimed subject matter obvious for at least these reasons.

Accordingly, Applicants respectfully request that the obviousness rejection with respect to Claims 1, 3-4, 6-10 and 13-20 be reconsidered and the rejection be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

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